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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,158	10/10/2006	Helen Frances Baker	GJE-7667	6154

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EXAMINER	
SOLOLA, TAOFIQ A	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,158	BAKER ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-15 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 improperly depends from claim 1 for failure to limit the scope of claim 1. The phrase "pharmaceutical composition . . . comprising" in line 1, claim 1, implies a carrier or excipient is inherently present in the composition. By deleting claim 2 the rejection would be overcome.

Claims 13-14 are confusing and therefore indefinite. The claims are drawn to "a" [singular] product having "combined" mefloquine and anti-TNF for separate or sequential administration. Separate or sequential administration requires mefloquine and anti-TNF to be separate, not combined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skead et al., WO 02/19994 A2, individually, and in view of Fischkoff et al., US 2004/0009172 A1.

Applicant claims compositions of (+)-mefloquine substantially free of the (-) enantiomer in unit doses of 5-60 mg. In preferred embodiments the composition is for treating inflammatory condition such as, osteoarthritis and rheumatoid arthritis, the compositions further comprise methroterxate (combination therapy), and may be used simultaneously, separately or sequentially.

Determination of the scope and content of the prior art (MPEP 2141.01

Skead et al., teach composition of (+)-mefloquine, which is at least 50-99 % (at least implies it may be 100 %) enantiomeric pure, for treating inflammatory disorders, such as osteoarthritis and rheumatoid arthritis. Skead et al., teach the dose can be readily determined by one skill in the art, taking into consideration, patient type, the nature of the disorder and route of administration. Skead et al., also teach methroterxate as useful for treating inflammatory disorders but, with serious side effect, while (+)-mefloquine has little side effect and maximum efficacy. See pages 1-2, paragraphs 2-3 and page 3, paragraphs 1-4.

Fischkoff et al., teach composition for treating inflammatory disorders comprising anti-TNF antibody. The composition further comprises and one or more drugs for treating inflammatory disorders, such as rheumatoid arthritis, autoimmune disorders, etc. and the composition may be used simultaneously, separately or sequentially (combination therapy). See [0006]-[0008].

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of the prior arts is that applicant claims unit doses of 5-60 mg.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, Skead et al., teach the dose can be readily determined by one skill in the art, taking into consideration, patient type, the nature of the disorder and route of administration. Also, combination therapy is well-known in the practice of medicine. Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art would have known how to determine the dose at the time this invention was made. The motivation is from the teaching of Skead et al., that the dose can be readily determined by one skill in the art, taking into consideration, patient type, the nature of the disorder and route of administration.

Alternatively, given Skead et al., dosing factors it would have been obvious to try and determine the dose at the time this invention was made.

When there is motivation

> to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, (+)-mefloquine, methroterxate, and their method of use to treat inflammatory disorders, are not applicant's invention. They are in the public domain prior to the time the instant invention was made. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done separately. *In re Anderson,* 396 U.S. 57, 163 USPQ 673 (1969)

cited in *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida,* 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra.* A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.,* 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra.*

Applicant's result of reduced side effect is expected since less methroterxate is used in the combination therapy due to expected synergistic effect thereof.

Specification

Brief descriptions of the figures are not in the specification.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

March 25, 2008